JUN 2 5 2014

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510(K) SUMMARY

Venus Swan (MP)^2 System

510(k) Number K140629

Applicant's Name: Venus Concept Ltd.
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Trade Name: ***Venus Swan (MP)^2***
Common Name: ***Swan (MP)^2***

Summary Preparation Date: March 4, 2014

Classification: **Classification Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI
Regulation No: 21 CFR 878.4400
Class: II
Panel: General and Plastic Surgery

Device Description:

The ***Venus Swan (MP)^2*** ™ System uses Radiofrequency (RF) energy in (MP)^2 technology for treatment. (MP)^2 technology is a Multi-Polar array of Bi-Polar RF electrodes together with Pulsed Magnetic Field (PMF).

The ***Venus Swan(MP)^2*** ™ is a modification to the previously cleared Venus Concept's ***Venus Swan*** system (K100586).

The ***Venus Swan (MP)^2*** is a noninvasive, non-ablative device consisting of:

- Main Unit (console)
- Touch Screen user interface
- RF Power module
- Controller unit

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- Two optional treatment applicators:

(1) Octipolar-M™ applicator – for medium sized treatment areas, composed of 8 RF electrodes, 8 electrode coils assembled over the electrodes and a central coil (the RF is emitted through the electrodes. The PMF is generated by the coils)

(2) Diamondpolar™ applicator – for small treatment areas, composed of 4 RF electrodes, 4 electrode coils (the RF is emitted through the electrodes. The PMF is generated by the coils).

Touch screen user interface provides:

- Applicator selection (Octipolar-M™ / Diamondpolar™)
- RF Power Output and Treatment Time parameter adjustments to fit individual patient's skin condition and anatomical site treated.
- Interval timer.
- Current treatment parameters display.

Controller unit

Two optional treatment applicators

The RF power module provides RF energy to the selected applicator, producing a 1MHz signal.

The magnetic field portion provides Pulsed Magnetic Field with magnetic flux density of 1.5mTesla (0.0015 Tesla or 15 Gauss). The frequency of the PMF is 15Hz.

Intended Use Statement:

The ***Venus Swan (MP)²*** system is a non-invasive device intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I- IV.

Predicate Devices: Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
Venus Freeze (MP)² System	**K111670**	March 2, 2010
Venus Swan System	**K111784**	October 7, 2011

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Performance Standards

Venus Swan (MP)² complies with

- ANSI AAMI 60601-2-2 for safety of high frequency surgical equipment.
- ***EN 60601-1*** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- ***IEC 60601-1-2*** (Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests)

Non clinical Performance Testing

The following performance tests were conducted:

Test Name	Purpose
RF Energy Test	Validate ***Venus Swan (MP)²*** power control and accuracy in reference to the user's input.
Power Failure Safety Test	The goal for this test is to validate ***Venus Swan (MP)²*** power control after external power failure.
STBY Mode Power Test	The goal for this test is to validate the ***Venus Swan (MP)²*** power control in STBY mode.
Electrode Safety Test	The goal for this test is to validate the safety of the ***Venus Swan (MP)²*** applicators by short-circuiting and open-circuiting the electrodes.
Magnetic flux density Test	Measure the magnetic flux density at the tissue level

Testing results show that the ***Venus Swan (MP)²*** System is safe and performs according to its specifications.

Materials and Biocompatibility

The ***Venus Swan (MP)²*** parts that come in contact with the patient or the user are identical to these parts in the cleared ***Venus Swan*** and therefore are biocompatible according to ISO 10993-1.

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Summary of Clinical performance data

The ***Venus Swan (MP)²*** implies the exact same RF frequency and power as the ***Venus Swan*** and the exact same RF frequency and magnetic field as the ***Venus Freeze (MP)²***. The applicators of ***Venus Swan (MP)²*** are the same as those of ***Venus Swan***, excluding ***Venus Swan***'s Octipolar-L applicator, except that the magnetic coils that are exactly the same as in the ***Venus Freeze (MP)²*** applicators. ***Venus Swan (MP)²*** uses power up to 120W whereas the ***Venus Swan*** and ***Venus Freeze (MP)²*** may use power up to 150 W. The maximum power difference is within the maximum power of the predicate devices and thus does not raise any new questions of safety and efficacy.

Venus conducted a clinical study with 31 subjects to support the effectiveness and safety of the subject Venus Swan $(MP)^2$ System and were followed for 3 months post last treatment. No unexpected adverse side effects were detected or reported. All subjects participating in the study reported no pain during the treatments.

Photographic analysis of pre-and post treatment of the digital images was conducted by uninvolved reviewers. Analysis revealed improvement in 83% of study subjects. The treatment met the expectations of 93% of the subjects enrolled.

Summary of Substantial Equivalence

The ***Venus Swan (MP)²*** like the ***Venus Freeze (MP)² System*** **(K111670)** combines the RF energy with Pulsed Magnetic Field (PMF) energy.

The power density and frequency of RF power parameters of the submitted ***Venus Swan (MP)² System*** are the same as in its predicate devices - ***Venus Freeze (MP)² System*** **(K111670)** and ***Venus Swan*** **(K111784)**.

Thus the ***Venus Swan (MP)²*** is substantial equivalence to its predicate devices without raising new questions of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2014

Venus Concept Ltd.
Yoram Levy
Quality Assurance/Regulatory Affairs Consult
62 HaHermesh Street
Karmiel, 21652 Israel

Re: K140629
Trade/Device Name: Venus Swan (MP)2
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 26, 2014
Received: May 26, 2014

Dear Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140629

Device Name
Venus Swan (MP)2

Indications for Use *(Describe)*
The Venus Swan (MP)2 system is a non-invasive device intended for use in dermatologic and general surgical procedures for females for the non-invasive treatment of moderate to severe facial wrinkles and rhytides in Fitzpatrick skin types I-IV.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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